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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,453	04/16/2001	Dan M. Granoff	CHIR-0283	1041

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EXAMINER

FIELDS, IESHA P

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 06/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,453

Applicant(s)

GRANOFF ET AL.

Examiner

Iesha P Fields

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1645

DETAILED ACTION

Applicant's Amendment filed February 4, 2001 (Paper No 10) has been received and entered. Claims 15-16 have been amended and claims 1-16 are pending in the instant application.

Response to Amendment

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

1. Claims 1 and 15 rejected under 35 U.S.C. 112, first paragraph, is **maintained**.

Applicants have asserted that the specification teaches the meaning of "vaccine". Applicants further assert that examples for measuring an immune response to the composition of the claimed invention are taught in the specification. Applicants further assert that one skilled in the art would could make and use the immunogenic composition taught by the applicant and further that undue experimentation would not be necessary to practice the claimed invention.

Applicant's arguments have been carefully considered but not deemed persuasive.

Art Unit: 1645

Claim 15 is rejected because it recites a "vaccine" which is not supported by the specification. Claim 1 has been included in this rejection only to the extent that claim 15 recites claim 1. As stated previously, the specification does provide reasonable enablement for making an immunogenic composition such as that recited in claim 1. The specification does not however provide support for using the immunogenic composition as a "vaccine". The Examiner agrees with the applicant that the specification teaches how to measure an immune response (i.e. examples 1,2 and figures 1A-B, 2A-B). Claim 15 however recites a vaccine, not how to measure an immune response. A vaccine "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557,1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). The applicant has not provided support for using the composition as a vaccine. It is well recognized in the art that it is unclear whether a single protein derived from a pathogen will elicit protective immunity. Ellis, R.W. (see Chapter 29 of "VACCINES" [Plotkin, S.A. et al., (ed.), published by W.B. Saunders Company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies... and thus protect the host against attack by the pathogen."

Art Unit: 1645

Since no working examples could be found in the specification for how the claimed composition could be used as a vaccine and because the art teaches of a lack of success in making such a vaccine due to poor immunogenicity one of ordinary skill in the art would be forced into undue experimentation. The applicant is invited to point out the page and line in the specification that provides support for making an effective "vaccine".

Claim Rejections - 35 USC § 102

2. Claims 1-16 rejected under 35 U.S.C. 102(b) as being anticipated by Anderson and Poro et al is withdrawn in view of Applicants arguments.

New Grounds for Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milagres et al. in view of Lieberman et al.

Art Unit: 1645

The claims are drawn to an immunogenic composition comprising an oligosaccharide conjugated to a carrier and an outer membrane protein.

Milagres et al. (FEMS Immun Med Microbiol 1996 Vol 13 pp. 9-17) teach of an immunogenic composition comprising two serogroups of *Neisseria meningitis* (NmB and NmC). Milagres et al. further teach that the composition may be used in vaccine preparations (See Entire Document).

Lieberman et al. (JAMA 1996 Vol. 275 (19) pp 1499-1503) teach of an immunogenic composition comprising a *Neisseria meningitis* oligosaccharide-protein conjugate. Lieberman et al. further teach that the immune carrier is CRM₁₉₇.

Given that 1) Milagres et al. has taught of an immunogenic composition comprising two serogroups of *Neisseria meningitis* and that 2) Lieberman et al. has taught of an immunogenic composition comprising a *Neisseria meningitis* oligosaccharide-protein conjugate it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make an immunogenic composition comprising an oligosaccharide conjugated to a carrier and an outer membrane protein. One would have been motivated to make such a composition and expect a reasonable amount of success in view of the results and teachings of Milagres et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers

Art Unit: 1645

for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ilesha Fields

June 12, 2002



MARK NAVARRO
PRIMARY EXAMINER